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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2014-N-0002]

Zoetis Inc., et al.; Withdrawal of Approval of New Animal Drug Applications for Combination Drug Medicated Feeds Containing an Arsenical Drug; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect the withdrawal of approval of new animal drug applications (NADAs) that appeared in the Federal Register of February 27, 2014 (79 FR 10976). That document listed an NADA for which a withdrawal of approval (WOA) was not intended and failed to remove all conditions of use associated with the withdrawn NADAs. This correction is being made to improve the accuracy of the animal drug regulations.

DATES: This correction is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is correcting a document amending the animal drug regulations to reflect the WOA of NADAs that appeared in the Federal Register of February 27, 2014 (79 FR 10976). That document listed an NADA for which a WOA was not intended

and failed to remove all conditions of use associated with the withdrawn NADAs. This correction is being made to improve the accuracy of the animal drug regulations.

In the preamble in rule FR Doc. 2014-02617 published on February 27, 2014 (79 FR 10976), make the following corrections:

On page 10976, in the second column, in the 4th line of the "SUMMARY" section, remove "69" and replace with "68".

On page 10977, appearing near the end of the page, "Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria, has requested that FDA withdraw approval of the following 16 NADAs and 8 ANADAs", is corrected to read "Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria, has requested that FDA withdraw approval of the following 15 NADAs and 8 ANADAs"; and on the same page in the table, the entry "013-461 3-NITRO (roxarsone)/AMPROL Plus (amprolium and ethopabate)." is removed. This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is corrected by making the following correcting amendments.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.195 [Amended]

2. In § 558.195, remove paragraph (e)(1)(vii).

§ 558.355 [Amended]

3. In § 558.355, remove and reserve paragraph (b)(3).

4. In § 558.635, revise paragraphs (d)(4)(v), (d)(4)(vi), and (d)(4)(vii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(d) * * *

(4) * * *

(v) Monensin as in § 558.355.

(vi) Salinomycin as in § 558.550.

(vii) Semduramicin as in § 558.555.

Dated: March 25, 2014.

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Center for Veterinary Medicine.

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